Sean R. Kelly (skelly@saiber.com)
SAIBER LLC
18 Columbia Turnpike
Suite 200
Florham Park, NJ 07932
973-645-4801

Counsel for Defendant and Counterplaintiff
Anchen Pharmaceuticals, Inc.

Anthony W. Shaw (shaw.anthony@arentfox.com)
Joshua T. Morris (morris.joshua@arentfox.com)
ARENT FOX LLP
1050 Connecticut Avenue, NW
Washington, DC 20036-5339
(202) 857-6000

Of Counsel to Defendant and Counterplaintiff
Anchen Pharmaceuticals, Inc.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, ASTRAZENECA LP, KBI-E INC., and POZEN INC.,	)
Plaintiffs,	)
v.	) Civil Action No. 3:11-cv-06348-JAP-DEA
ANCHEN PHARMACEUTICALS, INC.	)
Defendant.	)

AMENDED ANSWER AND COUNTERCLAIMS OF DEFENDANT ANCHEN PHARMACEUTICALS, INC. TO COMPLAINT FOR PATENT INFRINGEMENT

Pursuant to Fed. R. Civ. P. 15 (a)(1)(B), Defendant Anchen Pharmaceuticals Inc. ("Anchen")[1], by and through its undersigned attorneys, hereby submits this Amended Answer and Counterclaims to the Complaint for Patent Infringement of Plaintiffs AstraZeneca AB ("AZ AB"), AstraZeneca LP ("AZ LP"), KBI-E Inc. ("KBI-E"), and Pozen Inc. ("Pozen") (collectively "Plaintiffs"). Anchen's Amended Answer and Counterclaims drops the asserted defense of inequitable conduct, which renders Plaintiff's Motion to Strike that defense (ECF No. 27) moot. By making this amendment, Anchen does not waive and expressly reserves the right to assert a defense and counterclaims for inequitable conduct in a future pleading based on evidence revealed through discovery or other means, and to the full extent permitted by law, the Federal Rules of Civil Procedure, and this Court's Local Rules.

Anchen hereby answers and counterclaims as follows:

NATURE OF THE ACTION

1. Paragraph 1 states legal conclusions and legal argument to which no response is required. To the extent a response is required, Anchen admits that this action is purportedly based on the Patent Laws of the United States as found in 35 U.S.C. § 100, *et seq*. Anchen also admits that VIMOVO® pharmaceutical products are sold in the United States and that this case purportedly relates to ANDA No. 202767. Anchen denies the remaining allegations of Paragraph 1.

THE PARTIES

2. Admitted.

[1] All claims against Anchen Incorporated were dismissed on November 15, 2011. *See* November 15, 2011 Stipulated Consent Order (D.I. 11-1 and 12). Therefore, Anchen Pharmaceuticals, Inc. responds in this Answer only on behalf of Anchen Pharmaceuticals, Inc, and the responses herein should not be construed in any other manner.

3. Admitted.

4. Admitted.

5. Admitted.

6. Admitted.

7. Admitted.

8. Anchen admits that Anchen is a wholly-owned subsidiary of Anchen Incorporated.

BACKGROUND

The NDA

9. Admitted.

10. Anchen admits that VIMOVO® is approved for marketing for use to relieve the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, and to decrease the risk of stomach (gastric) ulcers in patients at risk of developing stomach ulcers from treatment with non-steroidal anti-inflammatory drugs (NSAIDs). Anchen is without sufficient knowledge to form a belief as to the remaining allegations of Paragraph 10 and so denies the same as they relate to Anchen.

The Patents-In-Suit

11. Anchen admits that what appears to be a copy of United States Patent No. 6,926,907 ("the '907 patent") is attached to the Complaint as Exhibit A, and that Exhibit A speaks for itself with respect to the issue date and the title. Anchen denies the remaining allegations of Paragraph 11 as they relate to Anchen.

12. Anchen admits that the face of the '907 patent indicates it is assigned to Pozen. Anchen is without information sufficient to form a belief as to the remaining

allegations of Paragraph 12, and so denies the same as they relate to Anchen.

13. Anchen admits that what appears to be a copy of United States Patent No. 6,369,085 ("the '085 patent") is attached to the Complaint as Exhibit B, and that Exhibit B speaks for itself with respect to the issue date and the title. Anchen denies the remaining allegations of Paragraph 13 .as they relate to Anchen

14. Anchen admits that the face of the '085 patent indicates it is assigned to AZ AB. Anchen is without information sufficient to form a belief as to the remaining allegations of Paragraph 14, and so denies the same as they relate to Anchen .

15. Anchen admits that what appears to be a copy of United States Patent No. 7,411,070 ("the '070 patent") is attached to the Complaint as Exhibit C, and that Exhibit C speaks for itself with respect to the issue date and the title. Anchen denies the remaining allegations of Paragraph 15 as they relate to Anchen.

16. Anchen admits that the face of the '070 patent indicates it is assigned to AZ AB. Anchen is without information sufficient to form a belief as to the remaining allegations of Paragraph 16, and so denies the same as they relate to Anchen.

17. Anchen admits that what appears to be a copy of United States Patent No. 7,745,466 ("the '466 patent) is attached to the Complaint as Exhibit D, and that Exhibit D speaks for itself with respect to the issue date and the title. Anchen denies the remaining allegations of Paragraph 17 as they relate to Anchen.

18. Anchen admits that the face of the '466 patent indicates it is assigned to AZ AB. Anchen is without information sufficient to form a belief as to the remaining allegations of Paragraph 17, and so denies the same as they relate to Anchen.

The ANDA

19. Anchen admits that it filed ANDA No. 202767 ("Anchen's ANDA") with

the FDA under 21 U.S.C. § 355(j) to obtain FDA approval to commercially manufacture, use, import, offer for sale, and sell in the United States naproxen and esomeprazole magnesium delayed release tablets in two strengths, namely 500 mg (naproxen) /20 mg (esomeprazole magnesium) and 375 mg (naproxen)/20 mg (esomeprazole magnesium) ("Anchen's ANDA Products."). Anchen denies the remaining allegations of Paragraph 19 as they relate to Anchen .

20. Admitted.

JURISDICTION AND VENUE

21. Paragraph 21 states a legal conclusion and legal argument to which no response is required. To the extent a response is required, Anchen concedes to appear before this Court for this particular matter. Anchen denies the remaining allegations of Paragraph 21 as they relate to Anchen.

22. Anchen admits it is in the business of developing, formulating, manufacturing, marketing, offering to sell, selling and commercializing generic pharmaceutical products. Anchen denies the remaining allegations of Paragraph 22 as they relate to Anchen.

23. Anchen denies the allegations of Paragraph 23 as they relate to Anchen.

24. Anchen admits that it is in the business of developing, formulating, manufacturing, marketing, offering to sell, selling and commercializing generic pharmaceutical products. Anchen denies the remaining allegations of Paragraph 24 as they relate to Anchen.

25. Denied as to Anchen.

26. Anchen admits it intends to market Anchen's ANDA Products before expiration of the patents-in-suit and that the FDA received ANDA No. 202767 from Anchen. Anchen denies the remaining allegations of Paragraph 26 as they relate to Anchen.

27. Admitted.

28. Paragraph 28 states a legal conclusion and legal argument to which no response is required. To the extent a response is required, Anchen concedes to appear before this Court for this particular matter. Anchen denies the remaining allegations of Paragraph 28 as they relate to Anchen.

29. Paragraph 29 states a legal conclusion and legal argument to which no response is required. To the extent a response is required, Anchen concedes to appear before this Court for this particular matter. Anchen denies the remaining allegations of Paragraph 29.

30. Admitted.

31. Anchen admits that it conducts business in the generic pharmaceutical industry and that both companies share the same address employees from both companies are intermingled; both companies share the same address, and both companies share officers and employees. Anchen denies the remaining allegations of Paragraph 31 as they relate to Anchen.

32. Admitted.

33. Paragraph 33 states a legal conclusion and legal argument to which no response is required. To the extent a response is required, Anchen concedes to appear before this Court for this particular matter. Anchen denies the remaining allegations of Paragraph 33 as they relate to Anchen.

34. Paragraph 33 states a legal conclusion and legal argument to which no response is required. To the extent a response is required, Anchen concedes to appear before this Court for this particular matter.

COUNT I

(INFRINGEMENT OF THE '907 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

35. Anchen incorporates by reference paragraphs 1-34 of this Answer.

36. Paragraph 36 states legal conclusions and legal argument to which no response is required. Anchen denies the remaining allegations of Paragraph 36 as they relate to Anchen.

37. Paragraph 37 states legal conclusions and legal argument to which no response is required. Anchen denies the remaining allegations of Paragraph 37 as they relate to Anchen.

38. Paragraph 38 states legal conclusions and legal argument to which no response is required. Anchen denies the remaining allegations of Paragraph 38 as they relate to Anchen.

39. Paragraph 39 states legal conclusions and legal argument to which no response is required. Anchen denies the remaining allegations of Paragraph 39 as they relate to Anchen.

40. Denied.

COUNT II

(INFRINGEMENT OF THE '085 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

41. Anchen incorporate by reference paragraphs 1-40 of this Answer.

42. Paragraph 42 states legal conclusions and legal argument to which no response is required. To the extent a response is required, Anchen admits it provided

Plaintiffs written notice of its Paragraph IV certification, certifying that each claim of the '085 patent is not infringed by the products or activities described in ANDA No. 202767, and that Anchen seeks approval to market the ANDA product before the patents-in-suit expire. Anchen denies the remaining allegations of Paragraph 42 as they relate to Anchen.

43. Admitted.

44. Paragraph 44 states legal conclusions and legal argument to which no response is required. Anchen admits that the ANDA Notice Letter speaks for itself as to an explanation regarding invalidity on the '085 patent. Anchen denies the remaining allegations of Paragraph 44 as they relate to Anchen.

45. Denied.

46. Denied.

47. Denied.

48. Denied.

49. Denied.

50. Denied.

COUNT III

(INFRINGEMENT OF THE '070 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

51. Anchen incorporates by reference paragraphs 1-50 of this Answer.

52. Paragraph 52 states legal conclusions and legal argument to which no response is required. To the extent a response is required, Anchen admits it provided Plaintiffs written notice of its Paragraph IV certification, certifying that each claim of the '070 patent is not infringed by the activities described in ANDA No. 202767, and that Anchen seek approval to market the ANDA product before the patents-in-suit

expire. Anchen denies the remaining allegations of Paragraph 52 as they relate to Anchen.

53. Admitted.

54. Paragraph 54 states legal conclusions and legal argument to which no response is required. Anchen admits that the ANDA Notice Letter speaks for itself as to an explanation regarding invalidity on the '070 patent. Anchen denies the remaining allegations of Paragraph 54 as they relate to Anchen.

55. Denied.

56. Denied.

57. Denied.

58. Denied.

59. Denied.

COUNT IV

(INFRINGEMENT OF THE '466 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

60. Anchen incorporates by reference paragraphs 1-59 of this Answer as if fully set forth herein.

61. Paragraph 61 states legal conclusions and legal argument to which no response is required. To the extent a response is required, Anchen admits it provided Plaintiffs written notice of its Paragraph IV certification, certifying that each claim of the '466 patent is not infringed by the activities described in ANDA No. 202767, and that Anchen seek approval to market the ANDA product before the patents-in-suit expire. Anchen denies the remaining allegations of Paragraph 61 as they relate to Anchen.

62. Admitted as to Anchen.

63. Paragraph 63 states legal conclusions and legal argument to which no response is required. Anchen admits that the ANDA Notice Letter speaks for itself as to an explanation regarding invalidity on the '466 patent. Anchen denies the remaining allegations of Paragraph 63as they relate to Anchen.

64. Denied.

65. Denied.

66. Denied.

67. Denied.

68. Denied.

PRAYER FOR RELIEF

Anchen denies that Plaintiffs are entitled to any of the relief that they seek in the prayer for relief or otherwise.

DEFENSES

Without any admission as to the burden of proof or as to any of the allegations in the Plaintiffs' Complaint for Patent Infringement, Anchen states the following defenses:

First Defense

1. Each purported claim for relief in Plaintiffs' Complaint for Patent Infringement is barred for failure to state a claim upon which relief can be granted.

Second Defense

2. Anchen's ANDA Product does not infringe, and would not infringe (directly, indirectly, contributorily or by inducement) any valid or enforceable claim of the patents-in-suit.

Third Defense

3. By reason of the prior art and/or statements and representations made to the United States Patent and Trademark Office during the prosecution of the applications that led to the issuance of the patents-in-suit, such patents are so limited that no claim can be construed as covering any Anchen activity or Anchen's ANDA product.

Fourth Defense

4. Each and every asserted claim of the patents-in-suit is invalid for failure to meet one or more of the requirements of Title 35, United States Code, including Sections 101, 102, 103, 112, 116, and/or for improper double patenting.

Fifth Defense

5. Anchen's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Sixth Defense

6. Plaintiffs' claims and requested relief are barred by the doctrine of estoppel.

Seventh Defense

7. Plaintiffs' claims and requested relief are barred by the doctrine of waiver.

Eighth Defense

8. Plaintiffs' claims and requested relief are barred by the doctrine of laches.

WHEREFORE, Anchen demands judgment in its favor and against Plaintiffs as follows:

(a) Dismissing Plaintiffs' Complaint for Patent Infringement with prejudice and denying each request for relief made by Plaintiffs;

(b) Holding the '466 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Anchen's ANDA Product and not infringed by any process used to make Anchen's ANDA Product;

(c) Holding the '070 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Anchen's ANDA Product and not infringed by any process used to make Anchen's ANDA Product;

(d) Holding the '085 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Anchen's ANDA Product and not infringed by any process used to make Anchen's ANDA Product;

(e) Holding the '907 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Anchen's ANDA Product and not infringed by any process used to make Anchen's ANDA Product;

(f) Holding the '466 patent and all its claims invalid;

(g) Holding the '070 patent and all its claims invalid;

(h) Holding the '085 patent and all its claims invalid;

(i) Holding the '907 patent and all its claims invalid;

(j) Awarding Anchen its attorneys' fees;

(k) Awarding Anchen its costs and expenses; and

(l) Awarding Anchen such other and further relief as the Court deems just and proper.

ANCHEN PHARMACEUTICALS, INC.'S
COUNTERCLAIMS

Anchen Pharmaceutical, Inc. ("Anchen"), by way of counterclaim against Plaintiffs-Counterdefendants Plaintiffs AstraZeneca AB, AstraZeneca LP, KBI-E Inc., and Pozen Inc. (collectively "Counterdefendants "), alleges the following:

The Parties

1. Anchen Pharmaceuticals, Inc. ("Anchen") is a corporation operating and existing under the laws of California, having its principal place of business at 9601 Jeronimo Road, Irvine, California 92618.

2. On information and belief, AstraZeneca AB ("AZ AB") is a corporation operating and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

3. On information and belief, AstraZeneca LP ("AZ LP") is a limited partnership operating and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

4. On information and belief, KBI-E Inc. ("KBI-E") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business in Wilmington, Delaware.

5. On information and belief, Pozen Inc. ("Pozen") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 1414 Raleigh Road, Chapel Hill, North Carolina 27517.

Jurisdiction

6. These claims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

7. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Counterdefendants, by bringing this action in this District, have consented to and are subject to personal jurisdiction in this district.

9. Venue is proper in this district under 28 U.S.C. §§ 1391(b) & (c).

Factual Background

10. United States Patent No. 6,926,907 ("the '907 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," issued on August 9, 2005.

11. United States Patent No. 6,369,085 ("the '085 patent"), entitled "Form of S-omeprazole," issued on April 9, 2002.

12. United States Patent No. 7,411,070 ("the '070 patent"), entitled "Form of S-omeprazole," issued on August 12, 2008.

13. United States Patent No. 7,745,466 ("the '466 patent"), entitled "Form of S-omeprazole," issued on June 29, 2010.

14. Upon information and belief, the '907 patent is assigned to Pozen.

15. Upon information and belief, the '085 patent is assigned to AZ AB.

16. Upon information and belief, the '070 patent is assigned to AZ AB.

17. Upon information and belief, the '466 patent is assigned to AZ AB.

18. The '907, '085, '070, and '466 patents (collectively the "patents-in-suit") are listed in the Food and Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") in connection with VIMOVO®.

19. On information and belief, VIMOVO® is the trade name under which Counterdefendants market, distribute naproxen and esomeprazole magnesium tablets for relieving the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, and decreasing the risk of stomach (gastric) ulcers in patients at risk of developing stomach ulcers from treatment with non-steroidal anti-inflammatory drugs (NSAIDs).

20. On information and belief, Counterdefendants have and continue to develop and commercialize VIMOVO® in the United States.

21. Anchen has submitted Abbreviated New Drug Application 202767 ("Anchen's ANDA") for 500 mg (naproxen)/20 mg (esomeprazole magnesium) and 375 mg (naproxen)/20 mg (esomeprazole magnesium) delayed release tablets ("Anchen's ANDA Product") to the FDA.

22. Anchen's ANDA includes confidential information concerning Anchen's ANDA Product.

FIRST COUNT
(Declaration of Non-Infringement of the Patents-in-Suit)

23. Anchen repeats and realleges paragraphs 1 through 22 of the counterclaims. Counterdefendants have asserted the patents-in-suit against Anchen.

24. Counterdefendants allege—and Anchen denies—that the claims of the patents-in-suit cover Anchen's ANDA Product.

25. The claims of the patents-in-suit do not, either literally or under the doctrine of equivalents, cover Anchen's ANDA Product. Thus, Anchen has not infringed and will not infringe any claim of the patents-in-suit by making, using, selling, offering for sale, marketing, or importing Anchen's ANDA Product.

26. Anchen and Counterdefendants have adverse legal interests, and there is a substantial controversy between Counterdefendants and Anchen of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the patents-in-suit.

27. Anchen is entitled to a judicial declaration that Anchen has not infringed and will not infringe any claim of the patents-in-suit by making, using, selling, offering for sale, marketing, or importing Anchen's ANDA Product.

SECOND COUNT
(Declaration of Invalidity of the Patents-in-Suit)

28. Anchen repeats and realleges paragraphs 1 through 27 of the counterclaims.

29. The patents-in-suit and all their claims are invalid under 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or for improper double patenting.

30. Counterdefendants allege—and Anchen denies—that the patents-in-suit are valid.

31. Anchen and Counterdefendants have adverse legal interests, and there is a substantial controversy between Counterdefendants and Anchen of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity of the patents-in-suit.

32. Anchen is entitled to a judicial declaration that the patents-in-suit are invalid.

WHEREFORE, Anchen demands judgment in its favor and against Plaintiffs as follows:

(a) Dismissing Counterdefendants' Complaint for Patent Infringement with prejudice and denying each request for relief made by Counterdefendants;

(b) Declaring the '907 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Anchen's ANDA Product and not infringed by any process used to make Anchen's ANDA Product;

(c) Declaring the '085 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Anchen's ANDA Product and not infringed by any process used to make Anchen's ANDA Product;

(d) Declaring the '070 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Anchen's ANDA Product and not infringed by any process used to make Anchen's ANDA Product;

(e) Declaring the '466 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Anchen's ANDA Product and not infringed by any process used to make Anchen's ANDA Product;

(f) Declaring all claims of the '907 patent invalid;

(g) Declaring all claims of the '085 patent invalid;

(h) Declaring all claims of the '070 patent invalid;

(i) Declaring all claims of the '466 patent invalid;

(j) Awarding Anchen its attorneys' fees;

(k) Awarding Anchen its costs and expenses; and

(l) Awarding Anchen such other and further relief as the Court deems just and proper.

Respectfully submitted,

SAIBER LLC
Attorneys for Defendant and Counterplaintiff Anchen Pharmaceuticals, Inc.

s/ Sean R. Kelly

Dated: January 31, 2012

Sean R. Kelly (skelly@saiber.com)
18 Columbia Turnpike
Suite 200
Florham Park, NJ 07932
(973) 645-4801

Anthony W. Shaw
(shaw.anthony@arentfox.com)
Joshua T. Morris
(morris.joshua@arentfox.com)
ARENT FOX LLP
1050 Connecticut Avenue, NW
Washington, DC 20036-5339
(202) 857-6000

Of Counsel to Defendant and Counterplaintiff Anchen Pharmaceuticals, Inc.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned counsel for Anchen hereby certifies, to the best of my knowledge, that the matter in controversy is not the subject of any other action pending in any court in this jurisdiction, or of any pending arbitration or administrative proceedings, except *AstraZeneca AB, et al. v. Lupin Ltd., et al.*, Civil Action No. 11-4275 (JAP)(DEA)(D.N.J.) and *AstraZeneca AB et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 11-2317 (JAP)(LHG)(D.N.J.).

Dated: January 31, 2012

s/ Sean R. Kelly
Sean R. Kelly

LOCAL CIVIL RULE 201.1 CERTIFICATION

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Anchen hereby certifies that Anchen seeks declaratory relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: January 31, 2012

s/ Sean R. Kelly
Sean R. Kelly